UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **MDL NO. 19-2875 (RBK)**

PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT* MOTION TO PRECLUDE DEFENSE EXPERT DAVID L. CHESNEY FROM OFFERING CLASS CERTIFICATION OPINIONS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

PRELIMINARY STATEMENT

Plaintiffs submit this *Daubert* motion against ZHP's cGMP expert David Chesney with regard to his class certification opinions – or lack thereof. Plaintiffs do not seek to exclude Mr. Chesney's opinions on the merits, as that phase has not been reached, but reserve the right to move on Mr. Chesney's substantive opinions in the future.

This motion is filed against the backdrop of the ongoing class certification briefing process and the clearly improper conduct of Defendants in the manufacture and sale of valsartan containing genotoxic impurities that are probable human carcinogens, NDMA and NDEA. As the Court is well aware, the NDMA and NDEA resulted from two pathways: (1) unsafe API manufacturing processes utilized by ZHP and Hetero, and (2) unsafe solvent recovery/re-use in the case of API manufactured by Mylan and Aurobindo, as well as the failure by the finished dose manufacturers to evaluate the API and identify the presence of the nitrosamines. The liability as to each defendant is well-suited for treatment through a class action since the wrongdoing impacted the products in common ways. For example, ZHP's failure to conduct an adequate risk assessment of the zinc chloride and triethylamine (with sodium nitrite quenching) manufacturing processes in violation of cGMPs resulted in the implementation of those processes and the output of valsartan API with NDMA and NDEA impurities. Similarly, the failure by ZHP to stop using its tainted manufacturing processes and notify its customers and regulatory authorities as soon as it became aware of the presence of the NDMA – in July 2017 at the latest – uniformly resulted in the continued use of the unsafe manufacturing process creating NDMA in the API.[1]

[1] The conduct of ZHP stands in stark contrast to that of Novartis, which evaluated ZHP's API before using it, and identified the NDMA – demonstrating how easily this entire episode could have been avoided with the application of minimal care by ZHP or its earlier customers.

Mr. Chesney is a former FDA employee, and attempted to deflect the allegations against ZHP in his report. Mr. Chesney offered substantive opinions though he was not required to do so at this stage (in contrast to Plaintiffs' GMP expert John Quick, who offered an overview and examples as context for his class certification opinions, and explicitly stated in his deposition that he had not done his full analysis to offer his full opinions on the merits; *i.e.*, 1/27/2022 Quick Tr. 107:12-19, 107:24-108:10, 252:10-13, Ex. 6). In contrast to his report, during the course of his deposition, Mr. Chesney conceded that ZHP violated cGMPs and that the violations rendered the entire API manufacturing process to be in violation of cGMP. He also agreed that this rendered all of the API made with that manufacturing process adulterated, and that the responsibility for this gross misconduct goes directly up the corporate ladder to ZHP Chairman Baohua Chen.

Turning to the specifics, though the class certification experts' task at this stage was to address the handling of the claims on a class basis, Mr. Chesney acknowledged that he has no opinions on class certification:

> Q. And I didn't see any opinions in your report regarding whether or not this matter was suitable or not for class certification. Am I correct that's not an issue you addressed?
>
> * * *
>
> A. That is not within my area of expertise, and I did not address it, no.

(Chesney Dep. Tr. 40:5-18, Ex. 1).[2]

He also confirmed that his opinions were limited to ZHP and the zinc chloride manufacturing process, as he did not consider any other parties, or ZHP's TEA manufacturing process:

[2] Unless otherwise noted, all exhibits are included in the certification of Adam M. Slater in support of this motion.

> Q. You've told me you didn't evaluate the TEA process, the triethylamine process, and you didn't talk about it in your report at all, right?
>
> A. That's correct.

(*Id.* at 24:1-6, 324:10-14). His opinions are "confined to ZHP and its manufacturing of the API," not its finished dose products, or anything regarding ZHP's wholly owned United States subsidiaries, "Prinston, Solco, or Huahai US." (*Id.* at 46:2-47:4).

Despite denying that he had considered or offered any opinions regarding class certification, Mr. Chesney actually admitted the predicates establishing the appropriate handling of these claims on a class basis. Mr. Chesney confirmed that, **"If you make the assumptions … as to the inadequacy of the risk assessment, … and the risk assessment violated GMP, … it [would] be a violation of GMP to then manufacture with that manufacturing process which is creating NDMA."** (*Id.* at 114:12-115:3). In other words, the GMP violations advanced by Plaintiffs and admitted later in the deposition by Mr. Chesney rendered the entire manufacturing process wrongful, and irreparably tainting the products of that process.

And proving the truth of these assumptions is not difficult. Plaintiffs have already presented the report of Stephen Hecht, Ph.D., on this subject. Dr. Hecht confirmed the inadequacy of the risk assessment by ZHP in the development of the zinc chloride manufacturing process. In short, ZHP failed to adequately evaluate the chemical processes, and failed to account for the risk of nitrosamine contamination." (*See* Hecht Rep., p. 18-21, Ex. 2).

Mr. Chesney **agreed** that the FDA's November 2018 Warning Letter to ZHP "summarizes significant deviations from current good manufacturing practices (CGMP) for active pharmaceutical ingredients (API)." (Chesney Dep. Tr. 320:24-321:6). The Warning Letter pointed directly to ZHP's failure to conduct a basic analysis of the potential chemical reactions in

the manufacturing process, specifically its "[f]ailure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API." (*Id.* at 328:6-12). The FDA explained:

> …In November 2011 you approved a valsartan API process change that included the use of the solvent DMF. Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, **you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant, dimethylamine.** According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

(*Id.* at 328:13-329:8). Mr. Chesney agreed that **"[t]he failure to adequately assess the potential formation of mutagenic impurities when ZHP implemented the new process, that would be a cGMP violation."** (*Id.* at 329:9-331:16).

Second, the FDA stated in the Warning Letter, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change," and **Mr. Chesney confirmed that this was a cGMP violation**. (*Id.* at 331:17-332:5). The FDA also told to ZHP: "You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients." Mr. Chesney agreed that this "was an obligation of ZHP." (*Id.* at 332:7-21).

Further, the FDA rejected ZHP's central but hopelessly flawed excuse for its misconduct throughout this litigation: **"Your response states that predicting NDMA formation during the**

valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree." (*Id.* at 334:8-16). Mr. Chesney conceded that the FDA "disagree[s] with ZHP [that predicting NDMA formation during the valsartan manufacturing process] required an extra dimension over current industry practice." (*Id.* at 335:3-10). Related, the FDA noted, **"We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce,"** and **Mr. Chesney agreed that this was ZHP's responsibility**. (*Id.* at 335:12-336:2).

An additional cGMP violation listed in the Warning Letter addressed the "ghost peaks," or in layman's terms the **"[f]ailure of [ZHP's] quality unit to ensure that quality-related complaints are investigated and resolved."** (*Id.* at 321:21-322:4). The FDA noted, "Our investigation also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms." (*Id.* at 326:2-7). It disagreed with ZHP's excuse:

> …"Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. **For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms where the presence of NDMA was expected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further**."
>
> * * *
>
> …"FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, **and because of the significant inadequacies in your investigation**."

(*Id.* at 326:8-328:3). Mr. Chesney agreed that he is not equipped to opine on this issue due to his lack of expertise. (*Id.* at 318:3-17).

Thus, Mr. Chesney admitted that ZHP violated cGMPs with respect to the zinc chloride process, rendering all of the valsartan-containing drugs manufactured with that process adulterated. As stated in the FDA Warning Letter: **"Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 USC 351(a)(2)(B)."** (*Id.* at 321:7-15). This misconduct is textbook for treatment on a class basis, and as stated above, Mr. Chesney avoided this reality by disclaiming any opinions related to class certification.

In addition to his substantive concessions, Mr. Chesney conceded that he had not seen or been provided highly relevant scientific materials and related deposition testimony that was available to counsel retaining him, all of which supported a finding that ZHP had violated numerous cGMPs. This begins with mainstream scientific evidence establishing the inadequacy of the ZHP risk assessment, all of which was identified and utilized in depositions of ZHP's corporate witnesses. For example, Mr. Chesney had never seen the IARC Monograph on the Evaluation of Carcinogenic Risk of Chemicals to Humans, *Some N-Nitroso Compounds*, Volume 17, dated May of 1978, despite its use in multiple 30(b)(6) depositions. (*Id.* at 117:3-10). "[P]age 36 of this IARC monograph, the third full paragraph … says, '**It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrate at an acidic pH yields N-nitrosodimethylamine,**'" which is NDMA. (*Id.* at 118:16-23).[3] **Mr. Chesney conceded that**

[3] The root cause of the NDMA is the reaction of dimethylamine and nitrous acid during the quenching phase of the process.

this is "the sort of thing I would expect scientific experts with whom I would collaborate to take into consideration." (*Id.* at 119:12-14).

Further, in refuting Mr. Chesney's net opinion/unfounded assumption that adequate means to test for NDMA did not exist in 2011 when the zinc chloride process was developed and adopted, he was shown that the 1978 IARC Monograph identified mass spectrometry as the proper method to test for the presence of nitrosamines: "The principal techniques employed for the analysis of volatile N-nitrosamines have been described in a recent publication (Preussmann et al, 1978). The relative merits of high- and low-resolution mass spectrometry are discussed, **since use of mass spectrometry as a confirmatory technique is particularly important**." (*Id.* at 120:12-121:8).[4]

The Purification of Laboratory Chemicals, a textbook first published in 1996 and then again multiple times thereafter, was another document that Mr. Chesney had never seen, even though it was the subject of multiple 30(b)(6) depositions. (*Id.* at 122:21-124:12). The textbook explains in simple terms that DMF (which was added as part of the creation of the zinc chloride process) can decompose/degrade to create dimethylamine: "DMF 'decomposes slightly at its normal boiling point to give small amounts of dimethylamine and carbon monoxide.'" (*Id.* at 123:21-125: 16). Mr. Chesney again confirmed, **"[T]his would be the type of feasibly available scientific information you would expect the people at ZHP to have been aware of when they were performing the risk assessment with regard to their decision to add DMF to the manufacturing process…."** (*Id.* at 125:17-126:4).

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[4] Mr. Chesney's adoption of ZHP's hollow refrain that the technological means to test for NDMA did not exist in 2011 was dismantled. Mr. Chesney conceded that if the scientific analysis should have disclosed the potential creation of nitrosamines, and if – as assumed in HIS hypothetical – there were not adequate means to test for nitrosamines in 2011, then ZHP would have had to abandon the process since one cannot sell a drug that potentially contains a genotoxic impurity like NDMA without first being able to test the product to prove it is not present. (*Id.* at 167:2-21).

Mr. Chesney was confronted with yet another scientific article that discussed the potential for dimethylamine to result from the use of DMF, also used in multiple 30(b)(6) depositions. The article is titled, "N-N-Dimethylformamide: much more than a solvent," dated in 2009, and states: "DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent." (*Id.* at 128:8-129:13). Mr. Chesney confirmed:

> I can agree that, from what you've shown me, that there are references in the scientific literature that are potentially useful data points that should be taken into account and considered in the overall scheme of things. . .
>
> * * *
>
> **It's information that's out there in the scientific literature. It would have been appropriate for them to take a look at it and give it consideration.**

(*Id.* at 130:4-12, 131:15-18).

Mr. Chesney was confronted with yet another relevant scientific article, "titled Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine," which states: "It is well known that N-nitrosamines are a class of undesired industrial and environmental pollutants, many of which are carcinogenic, mutagenic, and teratogenic. In particular, N-nitrosodimethylamine (NDMA), which is the simplest dialkylnitrosamine, has been demonstrated to be a potent carcinogen to various organs in animals, including liver, lung, and kidney." (*Id.* at 132:3-133:9-18). The article was published in 2010, authored by people working and studying at the College of Life Science & Bioengineering **at Beijing University of Technology in Beijing**. (*Id.* at 136:22-137:6). Mr. Chesney agreed, "There's long been a general awareness that unidentified impurities need to be characterized so you know what you're dealing with, and then

back up and look and see what the implications are of those materials present in your product as a result of your process, and to the extent feasible to quantitate them," and "if you identify either the **potential or the actual occurrence** of [a genotoxic] impurity, then certainly it's important to understand it." (*Id.* at 134:22-135:15).

Going back to demonstration of the inadequacy of ZHP's risk assessment, the article published by authors in Beijing in 2010 further states, "[B]ecause dialkylnitrosamines are of great interest in carcinogenesis, much attention have been focused on their formation mechanism, especially from secondary amines. Consequently, NDMA is generally believed to be formed from the reactions of dimethylamine (DMA) and nitrosating agents, such as N2O3, N2O4 and ONCl." (*Id.* at 136:7-17). Mr. Chesney confirmed that [redacted] *Id.* at 138:10-19). Mr. Chesney then attempted to hedge, stating that he would like to know from counsel if or how this information was factored in, but conceded that it had to be known and taken into consideration: "I would expect them to know that that information was out there. **But why they excluded it from consideration in their particular product would be what I'd like to hear their explanation of. I don't know if they would have such an explanation or not, but I would certainly ask them**, Is there anything about your particular process that led you to believe that information such as this would not be relevant. **But a lack of awareness that it exists or even to rule it out as important, no, I would expect them to go that far at least,**" as a matter of GMP. (*Id.* at 141:8-143:1).

Most important, he agreed: **"If you were to assume that considering that information could have feasibly led to testing to see if nitrosamines were being formed, if you assume that, and that that testing would have shown NDMA was being formed, then the failure to take this into consideration in 2011 would be a GMP violation…."** (*Id.* at 151:3-12). And that would be a violation impacting every pill manufactured with that unsafe process. And this is true despite the fact that ZHP had created this new manufacturing process:

> Q. So when ZHP decided to develop this zinc chloride process that had not been used before, they were responsible for the quality of the drugs that would be manufactured with that new process, right?
>
> * * *
>
> A. Yes, they were responsible.
>
> Q. And the fact that nobody else had been manufacturing by that process previously doesn't change the fact or excuse the fact that they failed to evaluate fully the risks from that new process?
>
> * * *
>
> A. The fact that nobody else was using the process does not relieve them of the necessity to evaluate it fully.

(*Id.* at 335:20-336:12).

Mr. Chesney also agreed, **"[R]isk assessment is not a static process, it's a process that continues through the lifecycle of the drug's production and manufacture," and "[i]f they are aware that a product contains a contaminant that poses an actual or potential danger to health, and tell no one and continue to ship it anyway, that could be construed later, after evaluation of all the facts, as having shipped a contaminated and, therefore, adulterated product in interstate commerce."** (*Id.* at 189:24-190:3, 195:16-23).

In the context of the ongoing risk assessment obligation, Mr. Chesney was questioned about yet another document he claimed to be completely unaware of, the July 27, 2017 email from Jinsheng Lin, Ph.D., to multiple high level executives at ZHP, stating as known fact that (1) there was NDMA in ZHP's valsartan, (2) the root cause was the quenching of the product with sodium nitrite, and (3) this was a problem with the manufacture of multiple sartans. (*Id.* at 208:20-209:12-211:10; ZHP00190573, Ex. 3). Mr. Chesney was first educated (as he should have been when he wrote his report) as to who Dr. Lin is, and where in ZHP he works, through a ZHP PowerPoint concerning ZHP's Center of Excellence for Modern Analytical Technologies (CEMAT). (Chesney Dep. Tr. 201:18-202:7). The PowerPoint describes CEMAT's [redacted] (*Id.* at 203:8-209:7). **The PowerPoint states** [redacted] (*Id.* at 205:3-10). [redacted]

[redacted] (*Id.* at 205:11-206:17). Thus, it was Dr. Lin's job to evaluate impurities such as the NDMA in valsartan. It is no surprise that he would know this. Further illustrating his information deficit, Mr. Chesney had no prior knowledge of CEMAT or Dr. Lin. (*Id.* at 206:18-207:1).

Mr. Chesney agreed that **"[i]f, as stated in this document, ZHP knew that there was NDMA in the valsartan and it was a process impurity that was being created when the sodium nitrite quenching step occurred as part of the zinc chloride process, then everything you said ZHP was required to do in June of 2018 would be transferred back to July of 2017, or whenever earlier date they knew this, and all those things would have been required at that time."** (*Id.* at 219:13-220:3).[5] He was then asked:

> If ZHP knew at least as of July 27, 2017 that there was NDMA in the valsartan, and kept that secret and didn't tell any customers or any regulators until Novartis came to them and forced them to disclose this information in June of 2018, that would be a violation of the Food, Drug and Cosmetic Act, correct?
>
> * * *
>
> A. It would if it was offered for importation into the United States, yes.

(*Id.* at 220:7-17).

Mr. Chesney was also shown that Dr. Lin's email stated in part:

> If it is confirmed as the above speculated structure, then **its toxicity will be very strong, and there will be an extremely high GMP risk**. This is a common problem in the production and synthesis of

[5] Mr. Chesney had confirmed earlier in his deposition that ZHP was required to take the steps it ultimately took to notify its customers and the regulatory authorities in June 2018, as soon as it knew of the NDMA and NDEA impurities, though he did not know at the time that ZHP had known almost a year earlier (at least) and had kept this critical information hidden. (*Id.* at 96:13-98:21).

> sartan APIs. It is recommended to improve other quenching processes (such as NaClO) along with the optimization of the valsartan sodium azide quenching process.
>
> * * *
>
> I've also attached a patent of a 2013 sodium azide NaClO quenching method by Zhejiang Second Pharma Co., Limited. They proposed that the use of NaNO2 quenching will result in the formation of N-NO impurities," which is N-nitroso impurities. "At the same time, they used ZHP's crude Valsartan in their LC-MS test" -- that would be liquid chromatography-mass spectrometry -- "and detected this impurity. This indicates that other companies have paid attention to the quality problem very early on. **So leaders please pay attention to this issue.**

(*Id.* at 223:8-19, 228:1-13), emphasis added. He agreed: "That is a very responsible thing to say in this e-mail, alerting the others that receive this e-mail of this situation with the creation of NDMA and the fact that it's a common problem in the production and synthesis of sartan APIs. It's responsible for him to tell the leaders in his company to take note of this situation…." (*Id.* at 229:11-18). However, we know that nothing was done in response, since in the words of Jun Du as documented by the FDA investigator: "[T]he purpose of the change was to save money. Mr. Du further stated the cost reduction was so significant it is what made it possible for the firm to dominate the world market share." (July/August 2018 EIR, p. 25. Ex. 4).

Mr. Chesney further confirmed that **"we know in retrospect that what Dr. Lin said about the valsartan quenching creating the NDMA and this being a common problem in the production and synthesis of sartan APIs, we know in retrospect he was 100 percent correct about those statements."** (Chesney Dep. Tr. 230:18-231:6). Again trying to hedge, he hoped: "I don't know what was done about this, whether this was a triggering point for further work that culminated in the notification to FDA and the recall, or what." (*Id.* at 232:2-5). Of course, that is

not what happened, and ZHP did not disclose the NDMA contamination of its valsartan until Novartis forced it to do so in June 2018.

Mr. Chesney ultimately indicated that he would like to ask ZHP's attorneys or employees for explanations or other evidence to refute the evidence shown to him during his deposition. Aside from the fact that there is no credible contrary explanation or evidence, his hope that there may be is clearly result-driven, given that he previously **"assumed [he was] provided all of the relevant documents."** (*Id.* at 275:7-10).

Moreover, he agreed that **"the leaders of the company, right up to the highest executive, would have the ultimate responsibility for this quality problem," and "as a matter of GMP that the information in this e-mail could not be ignored; it needed to be aggressively evaluated by the so-called, quote-unquote, leaders as soon as it was brought to their attention."** (*Id.* at 229:22-230:1, 230:9-16). In this context, Mr. Chesney agreed that Baohua Chen is ultimately responsible for ZHP's cGMP violations, consistent with an article Mr. Chesney wrote titled, "Executive Responsibility for Quality," in the book titled, "Quality Management Essentials, Expert Advice on Building a Compliant System." (*Id.* at 233:22-234:10). He wrote:

> **Executive commitment to quality in the pharmaceutical industry is critical, not only to ensure continuing profitability of the company, but also for the safety and well-being of patients and to meet the needs of healthcare providers who prescribe and use pharmaceutical products every day.**

(*Id.* at 234:24-235:9). Mr. Chesney agreed, "It would never be acceptable for ZHP or any other company to place profits over safety." (*Id.* at 235:14-18). The article continues:

> For these reasons, quality assurance (QA) and GMP compliance may be viewed differently in the pharmaceutical industry than in those industries where a reputation for high quality drives sales. Quality assurance may be viewed as a 'cost of doing business' or an internal 'police department' issuing directives that delay or prevent

> product release. **That viewpoint can result in a low priority being assigned to quality operations and resourcing, which can lead in turn to quality problems, regulatory difficulties, unnecessary expense, adverse publicity, lawsuits and investor disappointment.** All these consequences are preventable if executive managers understand the importance of the quality assurance function and treat it as a critical business operation just like other critical areas, such as strategic planning, financial management and others.
>
> * * *
>
> **In addition to the business benefits, health regulatory agencies around the world both require and expect top management to support a strong quality assurance function for their companies.**

(*Id.* at 236:23-238:11). Crucially, **"[t]op management would include, for example, the chairman of ZHP, Mr. Baohua Chen; he would fall within the context of top management."** (*Id.* 238:7-10). Mr. Chesney also discussed the part of his article that lists some "Common Mistakes Executive Teams Make," with number 3 being, **"Emphasizing production quotas and market demands to the extent that quality problems are overlooked or regarded as unimportant - worst case, deliberate coverup of known quality problems through falsification of records."** (*Id.* at 247:24-248:14). The article concludes:

> [T]here's a "growing consensus about the most critical quality management concepts. First among those is that **executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health.**"
>
> **And you would agree that within ZHP, the ultimate responsibility lies with the executive management team, correct?**
>
> * * *

A. **Yes**, I would agree it applies to ZHP and everybody else in the industry.

* * *

The last paragraph of this article says, **"Prudent management teams recognize this and support their quality units both philosophically and materially, with strong policies backed up by consistent actions, authority and resources. Failure to do so may have both serious business consequences for the company and potentially even personal consequences for individual executives."**

Again, **that's a statement that you believe would hold true for ZHP and any company in this industry, right?**

A. **Yes**, any company in this industry.

(*Id.* at 251:11-252:20). Mr. Chesney was then asked how his article related to Dr. Lin's July 27, 2017 email:

Q. Going back to the events of 2017, if ZHP knew that there was NDMA in its valsartan as of at least July 2017, yet continued to manufacture that valsartan with the zinc chloride process, didn't change anything, didn't tell anybody, every pill manufactured with that process would be adulterated, right?

* * *

A. I'm sorry, I'm giving some thought to the way you phrased that, not the concept, but just the phraseology.

If there was proven evidence that the process was contributing NDMA at harmful levels, and they allowed that to continue and continued to sell the product, and particularly if there was any deliberate effort to conceal that, then yes, that would be very serious.

(*Id.* at 252:21-253:15).

Plaintiffs now move to preclude Mr. Chesney from offering opinions on class certification, parties other than ZHP, the TEA manufacturing process, or finished dose products, none of which he has addressed.

LEGAL ARGUMENT

I.

THE *DAUBERT* STANDARD

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. "As a gatekeeper, courts are supposed to ensure that the testimony given to the jury is reliable and will be more informative than confusing." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017). Additionally, "[b]oth an expert's methodology and the application of that methodology must be reviewed for reliability." *Id.* at 791. The "specific way an expert conducts such an analysis must be reliable; '**all of the relevant evidence must be gathered**, and **the assessment or weighing of that evidence must not be arbitrary**, but must itself be **based on methods of [the relevant field].**'" *Id.* at 796.

This Court recently applied these principles in ruling on the *Daubert* motions filed in connection with the parties' general causation experts. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999). An "expert's opinions must be based on the methods and procedures of [the relevant field], rather than on subjective belief or unsupported speculation." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, "the expert must have 'good grounds' for his or her belief." *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis, and "*any* step

that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745. A court should also consider the methodology's error rate when assessing its reliability. *Paoli*, 35 F.3d at 742 n.8. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Id.* at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Furthermore, "*Daubert*'s gatekeeping requirement .... make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002*), aff'd,* 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

> (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.,* 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95. To this end, the Third Circuit has affirmed the exclusion of expert testimony that "failed to consistently apply the … methods … articulate[d], … deviated from or downplayed certain well-established principles of [the] field, and … inconsistently applied methods and standards to the data so as to support [an] a priori opinion." *Zoloft*, 858 F.3d at 792.

II.
DAVID CHESNEY SHOULD BE PRECLUDED FROM OFFERING CLASS CERTIFICATION OPINIONS

Mr. Chesney clearly testified that he has no opinions with regard to class certification, parties other than ZHP, the TEA manufacturing process, or finished dose products; thus, there is no opinion to "fit" into the case, much less a methodology to explore. (Chesney Dep. Tr. 40:5-18, 46:2-47:4, 24:1-6, 324:10-14). Thus, he cannot provide such opinions. *See Zoloft*, 858 F.3d at 800. (*See also* ECF 1946, 33:6-7).

Despite this, Defendants cite Mr. Chesney's report three times in their class certification briefing. First: "Plaintiffs make various false allegations about ZHP, including that it: (1) changed its manufacturing process to 'save money' and 'dominate the world market share'; and (2) failed to conduct an 'adequate' risk assessment, leading to an 'out of control' manufacturing process. See EL Br. at 9-11. These attacks are both irrelevant and directly contrary to the record." (ECF 2008, p. 10 (citing Ex. 194, Chesney Rep. at 53-59, Ex. 5)). In fact, Mr. Chesney admitted that "Jun[] Du told the FDA investigator that the zinc chloride process allowed them to increase their yield and lower their cost, and to thus dominate the world market for valsartan." (Chesney Dep. Tr. 245:12-19). As explained above, he also agreed that that the FDA's November 2018 Warning Letter to ZHP "summarizes significant deviations from current good manufacturing practices (CGMP) for active pharmaceutical ingredients (API)," including numerous ones concerning the inadequacy of ZHP's risk assessment. (*Id.* at 320:24-336:2). And then when confronted with scientific literature supporting the inadequacy of ZHP's risk assessment, Mr. Chesney confirmed, **"[T]his would be the type of feasibly available scientific information you would expect the people at ZHP to have been aware of when they were performing the risk assessment with regard to their decision to add DMF to the manufacturing process…."** (*Id.* at 125:17-126:4).

Given this record, Defendants cannot rely on the self-serving statements found in Mr. Chesney's report since definitively contradicted by his sworn testimony. *See Paoli*, 35 F.3d at 742, 745.

Defendant also wrote, "FDA did not declare any VCDs or API used to manufacture VCDs 'adulterated' until, at the earliest, November 29, 2018…." (ECF 2008, p. 18 (citing Ex. 194, Chesney Rep., 4-5, 18)). This statement referencing the warning letter to ZHP is misleading if intended to convey that the valsartan was not adulterated until that date. As stated above, the GMP violations tainted anything manufactured with the offending process, due to ZHP's inadequate risk assessment in 2011. Mr. Chesney agreed that **"If you make the assumptions … as to the inadequacy of the risk assessment, … and the risk assessment violated GMP, … it [would] be a violation of GMP to then manufacture with that manufacturing process which is creating NDMA."** (*Id.* at 114:12-115:3). Thus, ZHP's 2011 cGMP violation rendered all valsartan manufactured with that inadequately assessed process adulterated on a going forward basis. Thus, ZHP cannot rely on Mr. Chesney for the opinion that ZHP's valsartan only became adulterated on November 29, 2018. *See Zoloft*, 858 F.3d at 800.

Third, Defendants cite Mr. Chesney for the proposition that, "[a]t all relevant times prior to each manufacturer's recall, all VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs." (ECF 2008, p. 18 (citing Ex. 194, Chesney Rep. at 4-5, 49-50)). Although he makes this general argument in his report, Mr. Chesney never reviewed the USP monographs for valsartan, and his report does not discuss ZHP's drug master files or ANDAs for valsartan, which are not even included in his report's references. (*Id.* at 156:6-13; Chesney Rep., Ex. B). Thus, ZHP cannot rely on Mr. Chesney's net opinion in his report, without supporting foundation such as review of the documents in question or some sort of analysis. *See Paoli*, 35 F.3d at 742, 745.

CONCLUSION

For the foregoing reasons, Mr. Chesney should be precluded from offering any opinions related to whether the claims are appropriate for class treatment, opinions regarding subjects he did not evaluate or opine on, and nor should ZHP be permitted to rely on Mr. Chesney's opinions in an effort to oppose class certification to the extent that reliance is based on net opinions lacking adequate foundation and analysis.

Respectfully,

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